MED WATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting
by health professionals of adverse events
and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence #

Page ____ of ____

A. Patient Information

1. Patient Identifier	2. Age at time of event:	3. Sex	4. Weight
In confidence	or ---------- Date of birth: ___/___/_____	☐ female ☐ male	____ lbs or ____ kgs

B. Adverse Event or Product Problem

1. ☐ **Adverse event - and/or -** ☐ **Product problem (e.g., defects/malfunctions)**

2. Outcomes attributed to adverse event (check all that apply)

☐ death, date of death: __/__/_____ ☐ disability

☐ life-threatening ☐ congenital anomaly

☐ hospitalization - initial or prolonged ☐ other: _____

☐ required intervention to prevent permanent impairment/damage

3. Date of event: __/__/_____ **4. Date of this report:** __/__/_____

5. Describe event or problem:

6. Relevant test/laboratory data, including dates:

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

C. Suspect Medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 _____

#2

2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1	#1
#2	#2

4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 _____	#1 ☐yes ☐no ☐doesn't apply
#2	#2 ☐yes ☐no ☐doesn't apply

6. Lot # (if known)	7. Exp. date (if known)	8. Event reappeared after reintroduction
#1	#1	#1 ☐yes ☐no ☐doesn't apply
#2	#2	#2 ☐yes ☐no ☐doesn't apply

9. NDC # (for product problems only)

10. Concomitant medical products and therapy dates (exclude treatment or event)

D. Suspect Medical Device

1. Brand name:

2. Type of device:

3. Manufacturer name & address:	4. Operator of device ☐ health professional ☐ lay user/patient ☐ other: _____
6. Model # Catalog # Serial # _____ Lot # Other #	5. Exp. date __/__/_____
	7. If implanted, give date __/__/_____
	8. If explanted, give date __/__/_____

9. Device available for evaluation: (Do not send to FDA)

☐yes ☐no ☐returned to manufacturer on __/__/_____

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone no.

2. Health Professional?	3. Occupation	4. Also reported to
☐yes ☐no		☐ manufacturer ☐ user facility ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☐

FDA

Mail to:
MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

***or* FAX to:**
1-800-FDA-0178

FDA Form 3500 (6/93) **Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.**